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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/601,513	09/25/00	THALLER M	1303-102

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EXAMINER	
FIELDS, I	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/601,513	Applicant(s) THALLER ET AL.	
	Examiner Iesha P Fields	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Abstract

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. A virulent Staphylococcal strain recited in claim 1 includes virulent coagulase negative or positive species.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 14 is directed to DSMZ No. 11942 found in *Staphylococcus aureus*. *Staphylococcus aureus* which encompasses DSMZ No. 11942 would be found naturally in the environment if the bacterial strain is not isolated. Therefore DSMZ No. 11942 does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintergrating Co., 90 US 566 (1974);American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Innoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated Staphylococcus aureus strain DSMZ No. 11942..."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 5 and 14 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of the DSMZ No. 11942. It is not clear that DSMZ No. 11942 is known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of DSMZ No. 11942 is an unpredictable event. Although applicant has provided a written description of a method for making DSMZ No. 11942, it will not necessarily reproduce the strain that is chemically and structurally identical to those claimed.

Because one skilled in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the DSMZ No. 11942, a suitable deposit for patent purposes, evidence of public availability of the DSMZ No. 11942 and or evidence of the reproducibility without undue experimentation is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves

this specific matter to the discretion of each state. Amendment of the specification to recite the date of deposit and the completing the record, applicant may submit a copy of the contract with the deposit and maintenance of each deposit.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR § 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of the deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if the test is not done by the depository; and

7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contact with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the DSMZ No. 11942 described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F. 2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR § 1.801-1.809 for further information concerning deposit practice.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12-13 provide for the use of a polysaccharide but since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

3. Claims 1-4, 7, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Karamanos *et al.*

The claims are drawn to a method of process of making and detecting Staphylococcal antibodies in a biological fluid.

Karamanos *et al.* (Archives of Biochemistry and Biophysics Vol. 342 1997 pp.389-395) disclose a method of detecting Staphylococcal antibodies in blood serum. Karamanos *et al.* further disclose a method of detecting Staphylococcal antibodies which react with the polysaccharide produced by *Staphylococcus epidermis* (See Abstract). Karamanos *et al.* further disclose use of *Staphylococcal* antibodies in an immunochemical assay (See Material and Methods Section; Immunological Methods).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Karamanos* and *Hussain et al.* in view of McKenney *et al.*

The claims are drawn to a method of making a *Staphylococcal* polysaccharide comprising culturing a staphylococcal strain in a defined medium, homogenizing, centrifuging, desalting, and freezing the surnatant to obtain the polysaccharide.

The teachings of *Karamanos et al.* are set forth above.

Karamanos et al. does not teach of a method of making a *Staphylococcal* polysaccharide comprising culturing a staphylococcal strain in a defined medium, homogenizing, centrifuging, desalting, and freezing the surnatant to obtain the polysaccharide.

Hussain et al. (Journal of Medical Microbiology Vol. 34 1991 pp.143-47) teach of a chemically defined medium for slime production from Staphylococcus.

McKenney *et al.* (Infection and Immunity Vol. 66(10) 1998 pp.4711-20) teach of a a method of making a *Staphylococcal* polysaccharide comprising homogenizing, centrifuging, desalting, and freezing the surnatant of a Staphylococcal strain to obtain the polysaccharide (See Material and Methods Section; Purification of Polysaccharide).

Given that 1) Karamanos *et al.* has taught of a method of detecting Staphylococcal antibodies in blood serum which react with the polysaccharide produced by *Staphylococcus epidermis* and that 2) *Hussain et al.* has taught of a chemically defined medium for slime production from Staphylococcus and that 3) McKenney *et al.* has taught of a method of making a *Staphylococcal* polysaccharide it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to culture the bacteria in the defined medium taught by *Hussain et al.* and to isolate the polysaccharide of Staphylococcus as taught by McKenney *et al.* One would have been motivated to make a *Staphylococcal* polysaccharide in view of the teachings of McKenney *et al.* that the polysaccharide of Staphylococcus is involved in prosthetic infections.

5. Claims 1, 6 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis *et al.* in view of Fisher *et al.*

The claims are drawn to a method of detecting Staphylococcal antibodies reacting with a polysaccharide in a biological fluid.

Davis et al (Patent 992132) disclose several methods for preparing polysaccharides produced by *Staphylococcus.*

Although the reference appears to disclose the same product claimed by applicants, the reference does not disclose the products produced by the claimed process. However the purification of production of a product by a particular process does not impart novelty to a product when the product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner.

See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Therefore even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art.

See In re King, 107 F. 2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F. 2d 599, 601, 38 USPQ 143-145 (CCPA 1938); In re Bergy, 563 F. 2d 1031, 1035,

195 USPQ 344, 348 (CCPA 1977) vacated 438 US 902 (1978); and United States v. Ciba-Geigy Corp, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

Fisher *et al.* (WO 96/09321) disclose a method for identifying, making and isolating immunoglobulin and antigen useful for preventing, diagnosing, and treating Staphylococcal infection. Fisher et al further disclose a method for detecting IgG and IgM antibodies in a biological fluid (See especially Method of Isolating Immunoglobulin p.16 and Example 1 page 24). Fisher *et al.* further disclose a method for detecting Staphylococcal antibodies in combination with additives which may be used in diagnostic tests (i.e. diagnostic kits).

Given that 1) Davis et al has taught of several methods for isolating polysaccharides produced by *Staphylococcus* and that 2) Fisher *et al.* has taught of a method for identifying, making and isolating immunoglobulin and antigen useful for preventing, diagnosing, and treating Staphylococcal infection it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to detect Staphylococcal antibodies reacting with a polysaccharide in a biological fluid. One would have been motivated to detect Staphylococcal antibodies reacting with a polysaccharide in a biological fluid in view of the teachings of Fisher *et al. that Staphylococcal* infections have become a cause of human morbidity in hospital patients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

February 12, 2001

ALBERT NAVARRO
PRIMARY PATENT EXAMINER